K113113

Revised 510(K) PREMARKET NOTIFICATION SUMMARY

Name/Address of submitter: OT medical GmbH
Konsul-Smidt-Str. 8b
D-28217 Bremen/Germany

NOV 16 2012

Establishment Registration Number: 10033109

Contact Person: Sabine Schmahl
Phone ++49-421-557161-15
Fax ++49-421-557161-95

Date Revised Summary Prepared: November 14, 2012

Device Classification Name: Endosseous Implant and Accessories

Device Classification Regulation Number: 21 CFR 872.3640 and CFR 872.3630

Device Regulatory Status: Class II Special Controls

Trade Name: Endosseous Dental Implant system

Purpose: The purpose of this 510(k) is to obtain clearance for sale in the U.S.A. for theOT-F² Dental Implant System.

Predicate Devices: K053242 Pitt-Easy Dental Implant System

Device Description: The OT-F² implants are available in the diameters 3.8, 4.1 and 5.0mm. For the diameter 3.8 and 4.1mm there are 5 lengths: 8, 10, 12, 14 and 16 mm, for the diameter 5.0mm only 4 lengths: 8, 10, 12 and 14 mm. The implants are made from titanium grad 4 acc. to ASTM F-67. For prosthetic construction we offer a temporary abutment CreativeLine, titanium abutments straight NaturalLine, ball head abutments TecLine and a bar connection with ProfiLine. All abutments are made from titanium grad 5 acc. to ASTM F-136.

Indication for Use: The OT-F² Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

Technological Characteristics: The physical properties and designs of the additional implants and accessories in the OT-F² Implant System were compared with legally marketed predicate devices. The technological characteristics were comparable:

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Comparison of Properties and Features of OT medical's OT-F² dental implant to Predicate device

	OT-F2	**Pitt-Easy** (K053242)
Specification of Material	Titanium Grade 4 acc. to ASTM-F 67	Titanium Grade 4 acc. to ASTM-F 67
Exterior geometry	cylindrical, threaded	cylindrical, threaded
Maximum diameter [mm]	3.8/4.1/5.0	3.8/4.1/4.9
Implant lengths [mm]	8/10/12/14/16	8/10/12/14/16
surface treatment	acid etched	acid etched or Titanium Plasma Spray
pretreatment	non (without sand blasting)	non (without sand blasting)
Sterilization	gamma radiation with x-rays	gamma radiation with x-rays
	using Co60 irradiation, with a minimum dose of 25.0 kGy (2.5 m rads), creating a Sterility Assurance Level of 10-6.	using Co60 irradiation, with a minimum dose of 25.0 kGy (2.5 m rads), creating a Sterility Assurance Level of 10-6.
packaging	blister packaging in double - sterile condition	blister packaging in double - sterile condition
Abutments	Titanium Abutment: NaturalLine	Titanium Abutment: VDL Anatomic
Abutment Angle:	0°	0°
	Ball head Abutment: TecLine	Ball head Abutment: Kugelkopf
Abutment Angle:	0°	0°
	Temporary Abutment: Creative Line	Temporary Abutment: A.G.T
Abutment Angle:	0°	0°
	Bar Abutment: ProfiLine	Bar Abutment: Paracentric
Abutment Angle:	0°	0°
Accessories for implants:	cover screws for each implant, anodised	cover screws for each implant, anodised
Accessories for abutments	abutment screw for each abutment	abutment screw for each abutment

Indications and contraindications:

Because of the comprehensive range of implant diameters (3.80/4.10/5.00 mm) and lengths (8/10/12/14/16), there is a broad spectrum of indications for use provided there is sufficient vertical bone height and horizontal bone width. This means that even where there is extensive atrophy of the jaw up to a minimal height of 10 mm and minimal width of at least 2 mm greater than the planned implant diameter, OT-F² implants can still be used both in the upper and lower jaws. Here too the indication spectrum can be made even greater by means of surgical measures such as augmentation, bone spreading or splitting. The OT-F² implant is not only suitable for insertion into jaw bones where complete healing has already taken place (late implantation), but also for delayed insertion (6 – 8 weeks following tooth extraction) and also if the conditions are suitable for immediate implantation (directly following tooth extraction). In so doing the implant diameter must be chosen so that it completely fills the profile of the empty alveolus or ideally slightly expands it while taking account of the specifications of the prosthesis. Even with an immediate implantation, solid primary stability should always be achieved.

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- OT-F² implants are particularly suitable for use in the region of the lower central and lateral and upper lateral incisors.
- A balance function during articulation should generally be avoided.

Brief Discussion of Clinical Studies: Clinical studies were not conducted, or deemed necessary, for the purpose of this 510(k) submission.

Non-Clinical Testing:

	Submitted on
Validation Sterilization	
- Microbiological Performance MDS Test 103706-10	Oct. 19, 2011
- Dose mapping 3x	Oct. 19, 2011
Ageing Study over 5 years by MDS, Test 094466-10	Oct. 19, 2011
Surface analysis:	
Duddeck, D.: Quantitative and qualitative element-analysis of implant-surfaces by SEM	June 26, 2012
IGMHS Surface Test PB119-09	July 30, 2012
SEM Pictures F²	Oct. 26, 2012
Test Cytotoxicity abutments, MDS report no. 123335-20	July 30, 2012
MDS Report cleaning validation_116360-10	June 26, 2012

Brief Discussion of Engineering Studies: Engineering studies were conducted as per ISO standard 14801:2003 (E) – (Dentistry – Fatigue test for endosseous dental implants). Testing revealed a stable screw joint at the highest forces tested.

Conclusions Drawn: The OT-F² implant and associated components have the same intended use as, and technological characteristics similar to, the legally marketed predicate devices. The information and data provided in the submission demonstrates, that the proposed device is substancially equivalent to its declared predicate.

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Establishment Registration Number: 10033109

Contact Person: Sabine Schmahl
Phone: ++49-421-55 71 61-15
Fax: ++49-421-55 71 61-95

Date Revised Summary Prepared: November 14, 2012

Device Classification Name: Endosseous Implant and Accessories

Device Classification Regulation Number: 21 CFR 872.3640 and CFR 872.3630

Device Regulatory Status: Class II Special Controls

Trade Name: Endosseous Dental Implant System

Purpose: The purpose of this 510(k) is to obtain clearance for sale in the U.S.A. for the OT-F³ Dental Implant System.

Predicate Devices: K926354 Endopore Dental Implant System (Innova)
K971196 Endopore Dental Implant System (Innova)
K032140 Endopore Dental Implant System (Innova)

Device Description: The OT-F³ implants are available in the diameters 4.1 and 5.0mm. For each diameter there are 3 lengths: 5, 7 and 9 mm. For prosthetic construction we offer a temporary abutment CreativeLine, titanium abutments straight NaturalLine, ball head abutments TecLine and a bar connection with ProfiLine. All implants and abutments are made from titanium grad 5 acc. to ASTM F-136.

Indications for Use: The OT-F³ Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It is suitable for insertion in completely healed jaw bone (late implantation).

Technological Characteristics: The physical properties and designs of the additional implants and accessories in the OT-F³ Implant System were compared with legally marketed predicate devices. The technological characteristics were comparable:

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Comparison of Properties and Features of OT medical's OT-F³ dental implant to Predicate Device

	OT-F3	Endopore
Specification of Material	Titanium Grade 5 acc. to ASTM-F 136	Titanium Grade 5 acc. to ASTM-F 136
Exterior geometry	conical	conical
Angulation of corpus	12°	10°
Implant lengths [mm]	5/7/9	5/7/9
Maximum diameter [mm]	4.1 / 5.0	4.1 / 5.0
Uncoated area [mm]	1.2	1 respect. 2
surface treatment	sintered surface	sintered surface
pretreatment	non (without sand blasting)	non (without sand blasting)
material for surface treatment	Titanium powder from titanium grade 4 and grain size of 50-150µm	Titanium powder from titanium grade 4 and grain size of 50-150µm
sintering process	high vacuum at 1250°	high vacuum at 1250°
Sterilization	gamma radiation with x-rays	gamma radiation with x-rays
	using Co60 irradiation, with a minimum dose of 25.0 kGy (2.5 m rads), creating a Sterility Assurance Level of 10-6.	using Co60 irradiation, with a minimum dose of 25.0 kGy (2.5 m rads), creating a Sterility Assurance Level of 10-6.
packaging	blister packaging in double - sterile condition	pouches in double - sterile condition
Accessories for implants:	cover screws for each implant	cover screws for each implant

Brief summary on OT-F³:
The OT-F³ implants are available in diameters 4.10/5.00 mm and lengths of 5/7/9 mm. This presents a special indication range at sufficient available horizontal bone quantity.
Surgical measures such as augmentation, bone spreading or bone splitting and bone grafts should not be applied simultaneously with the implantation, but the bone should have finally healed completely prior to implant insertion. The OT-F³ implant is suitable only for insertion into completely long-term healed bone (late implantation). OT-F³ implants should not be inserted into strong cortical bone (D1) due to limited blood support.

Brief Discussion of Clinical Studies: Clinical studies were not conducted, or deemed necessary, for the purpose of this 510(k) submission.

Overview on Non-Clinical Testing:

	submitted on
Validation Sterilization	
- Microbiological Performance MDS Test 103706-10	Oct. 19, 2011
- Dose mapping 3x	Oct. 19, 2011
Ageing Study over 5 years by MDS, Test 094466-10	Oct. 19, 2011

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Surface analysis:	
Duddeck, D.: Quantitative and qualitative element-analysis of implant-surfaces by SEM	June 26, 2012
Material data:	
Endolab Shear Bonding strength ASTM F1044	June 26, 2012
IMA Test Report Tension Testing ENGLISH	June 26, 2012
IfW Report 4451 Metallographie	July 30, 2012
Biocompatibility:	
Test Cytotoxicity abutments, MDS report no. 123335-20	July 30, 2012
MDS Report cleaning validation_116360-10	June 26, 2012

Brief Discussion of Engineering Studies: Engineering studies were conducted as per ISO standard 14801:2003 (E) – (Dentistry – Fatigue test for endosseous dental implants). Testing revealed a stable screw joint at the highest forces tested.

Conclusions Drawn: The OT-F^3 implant and associated components have the same intended use as, and technological characteristics similar to, the legally marketed predicate devices. The information and data provided in the submission demonstrates, that the proposed device is substancially equivalent to its declared predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 16, 2012

Mrs. Sabine Schmahl
Export Manager and Foreign Registrations
OT Medical GmbH
Konsul-Smidt-Str. 8B
Bremen, Germany D-28217

Re: K113113
Trade/Device Name: Endosseous Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: October 24, 2012
Received: November 7, 2012

Dear Mrs. Schmahl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=1300092402

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number: K113113

Device Name: Endosseous Dental Implant System

Indication for Use: The OT-F³ Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It is suitable for insertion in completely healed jaw bone (late implantation).

Concurrence of CDRH Office of Device Evaluation

Prescription Use___X___ OR Over-the –counter Use_____.
(per 21 CFR801.109)

Mary S. Runner

Digitally signed by Mary S. Runner
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner, 0.9.2342.19200300.100.1.1=1300087950
Date: 2012.11.16 13:54:03 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number:_____